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Dated: September 29, 2008 Signature: _____
(Burton A. Amernick)



Docket No.: 21547-00298-US1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Andrew Dawood

Application No.: 10/506,632

Confirmation No.: 3407

Filed: September 7, 2004

Art Unit: 3732

For: A FIXTURE FOR ORTHODONTIC
ANCHORAGE AND OSSEO DISTRACTION
OF THE ALVEOLAR PROCESS, AND FOR
THE STABILIZATION OF TEMPORARY
PROSTHESES

Examiner: M. N. Bumgarner

CLAIM FOR PRIORITY AND SUBMISSION OF DOCUMENTS

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Alexandria, Virginia 22314

Dear Sir:

Applicant hereby claims priority under 35 U.S.C. 119 based on the following prior foreign application filed in the following foreign country on the date indicated:

<u>Country</u>	<u>Application No.</u>	<u>Date</u>
United Kingdom	02 05299.1	March 6, 2002

In support of this claim, a certified copy of the said original foreign application is filed herewith.

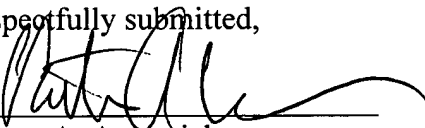
Application No.: 10/506,632

Docket No.: 21547-00298-US1

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 22-0185, under Order No. 21547-00298-US1 from which the undersigned is authorized to draw.

Dated: September 29, 2008

Respectfully submitted,

By 

Burton A. Amernick

Registration No.: 24,852

CONNOLLY BOVE LODGE & HUTZ LLP

1875 Eye Street, NW

Suite 1100

Washington, DC 20006

(202) 331-7111

(202) 293-6229 (Fax)

Attorney for Applicant

Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

undersigned, being an officer duly authorised in accordance with Section 74(1) and (4)
Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of
Comptroller-General, hereby certify that annexed hereto is a true copy of the documents
finally filed in connection with patent application GB0205299.1 filed on 6 March 2002.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named
in this certificate and any accompanying documents has re-registered under the Companies
Act 1985 with the same name as that with which it was registered immediately before re-
registration save for the substitution as, or inclusion as, the last part of the name of the words
"public limited company" or their equivalents in Welsh, references to the name of the
company in this certificate and any accompanying documents shall be treated as references to
the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c.,
plc, P.L.C. or PLC.

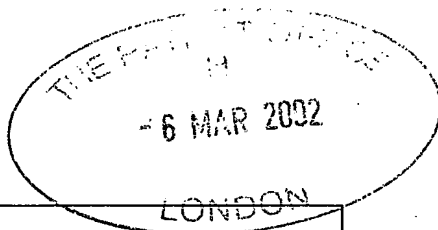
Re-registration under the Companies Act does not constitute a new legal entity but merely
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Signed

H. Behen

Dated 9 September 2008

For official use



07MAR02 E701346-1 C82929
P01/7700 0.00-0205299.1

Your reference

Notes

Please type, or write in dark ink using CAPITAL letters. A prescribed fee is payable for a request for grant of a patent. For details, please contact the Patent Office (telephone 071-438 4700).

Rule 16 of the Patents Rules 1990 is the main rule governing the completion and filing of this form.

Do not give trading styles, for example, 'Trading as XYZ company', nationality or former names, for example, 'formerly (known as) ABC Ltd' as these are not required.

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After an application for a Patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977 and will inform the applicant if such prohibition or restriction is necessary. Applicants resident in the United Kingdom are also reminded that under Section 23, applications may not be filed abroad without written permission unless an application has been filed not less than 6 weeks previously in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction revoked.

**The
Patent
Office**

Request for grant of a Patent

Form 1/77

Patents Act 1977

1 Title of invention

- 1 Please give the title of the invention **A FIXTURE FOR OSSEODISTRACTION OF THE ALVEOLAR PROCESS**

2 Applicant's details **06 MAR 2002 0205299.1**

☒ First or only applicant

- 2a If you are applying as a corporate body please give:

Corporate name

Country (and State
of incorporation, if
appropriate)

- 2b If you are applying as an individual or one of a partnership please give in full:

Surname **DAWOOD**

Forenames **ANDREW**

- 2c In all cases, please give the following details:

Address

**45 WIMPOLE STREET
LONDON**

UK postcode
(if applicable) **W1G 8SB**

Country **UK**

ADP number
(if known) **08338840001**

2d, 2e and 2f: If there are further applicants please provide details on a separate sheet of paper.

☐ **Second applicant (if any)**

2d If you are applying as a corporate body please give:

Corporate name

Country (and State
of incorporation, if
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2e If you are applying as an individual or one of a partnership please give in full:

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Forenames

2f **In all cases**, please give the following details:

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Country

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3 An address for service in the United Kingdom must be supplied

Please mark correct box

3 Address for service details

3a Have you appointed an agent to deal with your application?

Yes ☐ No ☒ go to 3b

↓
please give details below

Agent's name

Agent's address

Postcode

Agent's ADP
number

3b: If you have appointed an agent, all correspondence concerning your application will be sent to the agent's United Kingdom address.

3b If you have not appointed an agent please give a name and address in the United Kingdom to which all correspondence will be sent:

Name **ANDREW DAWOOD**

Address **45 WIMPOLE STREET
LONDON**

Postcode **W1G 8SB**

ADP number
(if known)

Daytime telephone
number (if available) **0207 935 8088**

④ Reference number

4 Agent's or
applicant's reference
number (if applicable)

⑤ Claiming an earlier application date

5 Are you claiming that this application be treated as having been filed on the date of filing of an earlier application?

Yes ☐ No ☒ → go to 6

↓
please give details below

☐ number of earlier
application or patent
number

☐ filing date
(day month year)

☐ and the Section of the Patents Act 1977 under which you are claiming:

15(4) (Divisional) ☐ 8(3) ☐ 12(6) ☐ 37(4) ☐

⑥ Declaration of priority

6 If you are declaring priority from previous application(s), please give:

Country of filing	Priority application number (if known)	Filing date (day, month, year)
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Please mark correct box

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⑥ If you are declaring priority from a PCT Application please enter 'PCT' as the country and enter the country code (for example, GB) as part of the application number.

Please give the date in all number format, for example, 31/05/90 for 31 May 1990.

- 7 The answer must be 'No' if:
- any applicant is not an inventor
 - there is an inventor who is not an applicant, **or**
 - any applicant is a corporate body.

8 Please supply duplicates of claim(s), abstract, description and drawing(s).

Please mark correct box(es)

- 9 You or your appointed agent (see Rule 90 of the Patents Rules 1990) must sign this request.

Please sign here ➡

A completed fee sheet should preferably accompany the fee.

7 Inventorship

7 Are you (the applicant or applicants) the sole inventor or the joint inventor?

Please mark correct box

Yes ☒

No ☐

A Statement of Inventorship on Patents Form 7/77 will need to be filed (see Rule 15).

8 Checklist

8a Please fill in the number of sheets for each of the following types of document contained in this application.

Continuation sheets for this Patents Form 1/77

Claim(s)

Description

Abstract

Drawing(s)

8b Which of the following documents also accompanies the application?

Priority documents (please state how many)

Translation(s) of Priority documents (please state how many)

Patents Form 7/77 – Statement of Inventorship and Right to Grant (please state how many)

Patents Form 9/77 – Preliminary Examination/Search

Patents Form 10/77 – Request for Substantive Examination

9 Request

I/We request the grant of a patent on the basis of this application.

Signed

ABJ

Date

06/03/02
(day month year)

Please return the completed form, attachments and duplicates where requested, together with the prescribed fee to either:

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A Fixture for Osseodistraction of the Alveolar Process

Dental implants are fixtures, which may be inserted into the jawbones in order to support dental prostheses. For, many reasons, there are often situations in which there is inadequate bone available in which to place fixtures.

In these situations, various techniques exist which may be used to augment the available bone bulk.

Osseo-distraction (distraction Osseo-genesis) is a surgical process by which the available bone bulk may be increased. This process may be used where there is a local deficiency in jawbone height, prior to the provision of implant-stabilised prostheses. Surgery involves sectioning a segment of the jaw, which must be pedicled on the surrounding soft tissue.

Subsequently, soft tissues are allowed to heal and the bone callus to develop. However after a few days latency, the bony "transport " segment is distracted, thus stretching the healing callus. Distraction proceeds incrementally, and substantial volumes of new bone may be laid down between the transport segment and the bony jaw base.

Varied fixtures and mechanisms have been developed to facilitate this process.

This invention relates to a fixture which when inserted into the transport segment will facilitate the distraction process in conjunction with attachments to adjacent teeth or fixtures. A specific embodiment of this invention will now be described with reference to figures 1 and 2.

With reference to Figure 1, there is provided a fixture, which may be made of machined titanium or a machined titanium alloy. The fixture may broadly be categorised as containing three segments.

An alignment section (1) is provided having a smooth surface, and relatively small diameter. A bone interfacing (2) retentive section is provided having a deep-set steeply pitched thread on a slightly tapered base (taper exaggerated in diagram).

A non-axially symmetrical collar (3) facilitates insertion of the device by means of a matched insertion tool, which fits over the intra oral part (4) of the fixture, rather like a socket spanner. This part is polished to allow a gingival cuff to develop around the fixture.

The intra oral part of the fixture (4) comprises a narrow extension provided with a machine screw threading.

Surgery proceeds as follows, with reference to figures 1& 2:

Following elevation of a surgical flap, a horizontal osteotomy is performed (A) at the base of the future transport segment (B).

Before the transport section is mobilized by the vertical osteotomies (C) , a site is prepared for the distraction fixture or fixtures; having marked the site with a round burr a 1.2mm twist drill is inserted beyond the depth of the horizontal osteotomy, such that it the site is prepare in bone of good bulk and quality.

A second twist drill is then inserted into the prepared site, having a slightly greater diameter, e.g. 1.6mm, to the depth of the horizontal osteotomy

If visibility and access to the site is unimpaired the surgeon may then continue to carry out the vertical osteotomy, thus freeing the transport section. However generally the osteotomy is only carried out to an extent, which will allow the transport segment to be easily mobilized once the fixtures have been placed.

The distraction fixture is then placed by means of an insertion tool that properly mates with the non-axially symmetrical collar such that the alignment section (1) travels through the narrowly prepared depth of the site. The threaded section (2) is tapped through the prepared site such that it engages the transport segment.

The threaded intra oral section (4) then protrudes into the mouth such that it is aligned with adjacent teeth or fixtures, and the main bulk of the bone is in the intended trajectory.

Following latency, or healing period of four-seven days distraction may begin. For distraction to take place there may be provided either a temporary prosthesis which serves to provisionally replace the missing teeth, or a simple appliance, (D), which may take the form of a cast bar, resin reinforced structure, or orthodontic appliance anchored to adjacent teeth or fixtures.

A prosthesis or appliance may be provided with a portion through which the threaded part of the distraction implant protrudes. Distraction may then be accomplished by tightening a nut (5) onto the machined threaded section so as to pull it through the channel, thus distracting the bony segments. As the portion of the threaded section protrudes past the nut, it may be sectioned so as to avoid interference within the mouth. Once distraction has taken place to the planned extent the arrangement is left in place for a subsequent period of six-eight weeks until the transport segment has stabilised, and bone has formed in the space between the segment and the bony base.

An orthodontic appliance may be fitted with a novel component which is designed to fit onto the arch wire of a fixed appliance, and mate with the head of the distraction fixture, thus allowing the distraction process to be controlled accurately in three dimensions.

Where distraction must take place over a substantial span, there may also be provided extension pieces (6) having an internally threaded tube at one end, which may be rotated over the threaded head of the fixture, and a nut at the other end to permit the piece to be rotated into place, and allow distraction to take place

Claims

1. A fixture having external threading, comprising, 1/ a threaded Part for insertion into a prepared site in the jaw bone, and 2/ a threaded part, to which pressure may be applied by means of an internally threaded element e.g. a nut, when used in conjunction with an appliance supported by teeth or adjacent static fixtures.
2. A one piece implant for osseodistraction, having a threaded part for insertion into bone, with the characteristics of a dental implant for insertion into bone, at one end, and the characteristics of a machine screw at the other end, which is intended to protrude into the mouth.
3. A fixture as described in previous claims, having two externally threaded parts, one which is inserted into a prepared site into the jaw bone, the other which protrudes into the oral cavity so that it may be acted upon by an internally threaded component eg a nut.
4. A fixture as described in the previous claim having a smooth, parallel sided alignment section at its' apex, intended to guide the transport segment of bone as it is distracted and prevent inappropriate movement.
5. A fixture as described in previous claims, which is provided with a polished section, intended to act as a collar to which the gingival cuff will approximate, said collar having a non round cross-section to allow insertion of the fixture with an appropriate shaped socketed tool.
6. A fixture as described in previous claims intended for connection to prostheses, orthodontic appliances, or adjacent teeth or dental implants.
7. A fixture as described in previous claims having a slightly tapered part, having deeply biting threads, on that part intended for insertion into the jaw, and a metric machine thread on that part intended to protrude through the gingiva.
8. A fixture intended for osseodistraction in the jaw, substantially as described in this description and the accompanying figures.

Figure 1

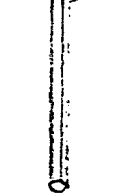
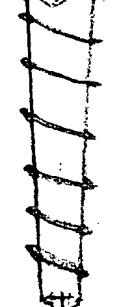
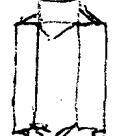
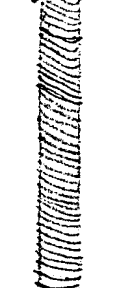
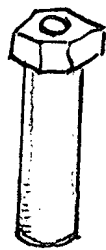


Figure 2

